JC06 Rec'd PCT/PTO 1.0. ALLG 2005

Approved for use through 3/31/2007. OMB 0651-0021

U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

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u .	TRANSMITTAL LETTER TO THE UNITED STATES DESIGNATED/ELECTED OFFICE (DO/EO/US) CONCERNING A SUBMISSION UNDER 35 U.S.C. 371 ATTORNEY'S DOCKET NUMBER BTG0005-100 (143593US01) U.S. APPLICATIV 10/5104310 #	3)
INTER	RNATIONAL APPLICATION NO. INTERNATIONAL FILING DATE PRIORITY DATE CLAIMED	-
PCT/	7/GB03/01512 04 April 2003 (04.04.2003) 05 April 2002 (04.05.2002)	
	OF INVENTION Y-DOSE POTASSIUM SUPPLEMENTATION FOR THE PREVENTION AND TREATMENT OF HYPERTE	
	ICANT(S) FOR DO/EO/US Express Mail Label No: EV514	_
Dona	ald Johnstone Naismith and Alessandro Braschi Date of Deposit: مورى عن المعاملة عند المعاملة	0, 2005
Applica	ant herewith submits to the United States Designated/Elected Office (DO/EO/US) the following items and other information:	
1. L	This is a FIRST submission of items concerning a submission under 35 U.S.C. 371.	
2.	This is a SECOND or SUBSEQUENT submission of items concerning a submission under 35 U.S.C. 371.	
3. (This is an express request to begin national examination procedures (35 U.S.C. 371 (f)). The submission must include items (5), (6), (9) and (21) indicated below.	
4.	The US has been elected (Article 31).	
5.	A copy of the International Application as filed (35 U.S.C. 371(c)(2))	
	a. is attached hereto (required only if not communicated by the International Bureau).	
	b. has been communicated by the International Bureau.	
_	c. is not required, as the application was filed in the United States Receiving Office (RO/US).	
6.	An English language translation of the International Application as filed (35 U.S.C. 371(c)(2)).	
	a. is attached hereto.	
_	b. has been previously submitted under 35 U.S.C. 154(d)(4).	
7.	Amendments to the claims of the International Application under PCT Article 19 (35 U.S.C. 371(c)(3))	
	a. are attached hereto (required only if not communicated by the International Bureau).	
_	b. have been communicated by the International Bureau.	
	c. have not been made; however, the time limit for making such amendments has NOT expired.	
_	d. L. have not been made and will not be made.	
8.	An English language translation of the amendments to the claims under PCT Article 19 (35 U.S.C. 371(c)(3)).	
9.	An oath or declaration of the inventor(s) (35 U.S.C. 371 (c)(4)).	
10.	An English language translation of the annexes of the International Preliminary Examination Report under PCT Article 36 (35 U.S. C. 371 (c)(5)).T	-
11	Items 11 to 20 below concern document(s) or information included:	
11.	An Information Disclosure Statement under 37 CFR 1.97 and 1.98.	
12.	An assignment document for recording. A separate cover sheet in compliance with 37 CFR 3.28 and 3.31 is included.	
13.	A preliminary amendment.	
14.	An Application Data Sheet under 37 CFR 1.76.	
15.	A substitute specification.	
16.	A power of attorney and/or change of address letter.	
17.	A computer-readable form of the sequence listing in accordance with PCT Rule 13ter.2 and 37 CFR 1.821- 1.825.	
18.	A second copy of the published International Application under 35 U.S.C. 154(d)(4).	
19.	A second copy of the English language translation of the international application under 35 U.S.C. 154(d)(4).	
20.	Other items or information: Forms PTO SB/08a and SB/08b (4 pp.); (37) References Cited and (36) References Enclosed; Copy Search Report dated August 6, 2003 for International Application No. PCT/GB03/01512.	of International

This collection of information is required by 37 CFR 1.414 and 1.491-1.492. The information is required to obtain or retain a benefit by the public, which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11 and 1.14. This collection is estimated to take 15 minutes to complete, including gathering information, preparing, and submitting the completed form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Mail Stop PCT, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

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10/510,370 [°]	0/510,370' INTERNATIONAL APPLICATION PCT/GB03/01512					ATION NO.		005-100 (14	
	o fees	are submitted:		1 0170000010101				CULATIONS	PTO USE ONLY
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22. Examinat	tion fe	e							
If International preliminary examination report prepared by USPTO and all claims satisfy provisions of PCT Article 33(1)-(4) \$10									
	All other situations\$200								
23. Search fe									
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Independent claims			-3 =			x \$200	\$	-	
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	NOTE: Where an appropriate time limit under 37 CIFIR 1.495 has not been met, a petition to revive (37 CFR 1.137(a) or (b)) must be filed and granted to restore the international Application to pending status.								
SEND ALL CORR					_		•		
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1900 Market Street Paul K. Legaard, Ph.D.									
Philadelphia, F	οΔ 10	9103			ме 3,534				
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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of: Naismith and Braschi

Serial No.: 10/510,370

Group Art Unit: To Be Determined

Filing Date: May 9, 2005

Examiner: To Be Determined

For: LOW-DOSE POTASSIUM SUPPLEMENTATION FOR THE PREVENTION

AND TREATMENT OF HYPERTENSION

EXPRESS MAIL INFORMATION

Express Mail Label No: EV514684935US

Date of Deposit: AUGUST 10, 2005

MAIL STOP AMENDMENT

Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

Dear Sir:

INFORMATION DISCLOSURE STATEMENT

Pursuant to 37 C.F.R. §§ 1.56 and in accordance with 37 C.F.R. §§ 1.97 and 1.98, information relating to the above-identified application is hereby disclosed, the Examiner in charge of the above-identified application is requested to consider and make of record the references listed on the PTO Forms SB/08A and SB/08B, formerly known as PTO Form 1449 submitted herewith.

Inclusion of the information submitted herewith is not to be construed as an admission that the information is material as that term is defined in 37 C.F.R. § 1.56(b).

In accordance with 37 C.F.R. § 1.97(g), the filing of this Information Disclosure Statement shall not be construed to mean that a search has been made.

This Informat	on Disclosure	Statement i	s being	filed:
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	within three months of the filing date of the patent application.
	within three months of the date of entry into the national stage as set forth in
	37 C.F.R. § 1.491 of the international application.
\boxtimes	before the mailing date of a first Office Action on the merits.

aitti t	he mailing date of a first Office Action on the merits, but before the
mailin	g date of a Final Office Action under 37 C.F.R. § 1.116 or a Notice of
Allowa	ance under 37 C.F.R. § 1.311, and accordingly is accompanied by:
	the Statement under 37 C.F.R. § 1.97(e) (see "Statement" below);
	or
	the Fee of \$180.00 set forth in 37 C.F.R. § 1.17(p); or
	No fee is owed by the applicant(s).
Statem Final S C.F.R.	ordance with 37 C.F.R. § 1.129(a), this Information Disclosure tent is being filed in connection with the first or second After Submission, and accordingly is accompanied by the Statement under 37 § 1.97(e) (see "Statement" below) and the fee of \$180.00 as set forth in I.R. § 1.17(p), is attached.
Notice Issue F	the mailing date of a Final Office Action under 37 C.F.R. § 1.116 or a of Allowance under 37 C.F.R. § 1.311, but before the payment of the Fee, and accordingly is accompanied by the Statement under 37 C.F.R. (e), (see "Statement," and "Fees" below).
SB/081 Interna	s of the references listed on the attached PTO Forms SB/08A and B, formerly known as PTO Form 1449 are enclosed. A copy of the ational Search Report dated August 6, 2003 for International Application CT/GB2003/01512, is enclosed.
EXCE	PT THAT:
	In view of the voluminous nature of reference @@, and the likelihood that this reference is available to the Examiner, copies are not enclosed herewith.
	In accordance with 37 C.F.R. § 1.98(d), copies of the references A-J listed on the attached PTO Form SB/08A, formerly known as PTO Form 1449 are not enclosed herewith because they were previously cited by or submitted to the U.S. Patent and Trademark Office in patent application(s) for which a claim for priority under 35
	Alloward All

	☐ If any of the foregoing publications are not available to the Examiner.
	Applicant will endeavor to supply copies at the Examiner's request.
Stater	nent under 37 C.F.R. § 1.97(e)
	The undersigned attorney hereby states that each item information contained in the Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign patent application not more than three months prior to the filing of the Information Disclosure Statement.
Fees	
\boxtimes	No Fee is owed by the applicant(s).
	The Information Disclosure Statement Fee of \$180.00 under 37 C.F.R. § 1.17(p) is enclosed herewith.
Metho	od of Payment of Fees
	Attached is a check in the amount of \$ This form is submitted in duplicate.
	Charge Deposit Account No. 50-1275 in the amount of \$180.00. This form is submitted in duplicate.
\boxtimes	Please charge any deficiency or credit any overpayment to Deposit Account 50-1275.
	No fee or Statement is required under 37 C.F.R. § 1.97(b).
	Respectfully submitted,

Paul K. Legaard, Ph.D. Registration No. 38,534

Dated: 10 AUGUST 2005

COZEN O'CONNOR, P.C. 1900 Market Street, 5th Floor Philadelphia, PA 19103-3508 (215) 665-2000 – Telephone (215) 701-2013 - Facsimile

JC20 Rec'd PCT/PTO 1 0 AUG 2005

PTO/SB/08a (08-03)

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	Substitute	for form 1449A/PTC				Complete if Known	
				•	Application Number		
	INFO	RMATION	DIS	CLOSURE	Filing Date	May 9, 2005	
	STAT	TEMENT B	Y A	PPLICANT	First Named Inventor	Donald Johnstone Naismith	
					Art Unit	To Be Determined	
		(Use as many she	ets as	necessary)	Examiner Name	To Be Determined	
abla	Sheet	1	of	4	Attorney Docket Number	BTG0005-100 (143593US01)	J

	U.S. PATENT DOCUMENTS						
Examiner Cite	Document Number	Publication/Issue Date	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant			
	No.1	Number - Kind Code ² (if known)	MM-DD-YYYY	Cited Document	Passages or Relevant Figures Appear		
	AA	US-4,855,289	08-08-1989	Wester et al.			
		US-					
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	0.11	Foreign Patent Document	0 155	Name of Patentee or	Pages, Columns, Lines,	
Examiner Initials*	Cite No. ¹	Country Code ³ - Number ⁴ - Kind Code ⁵ (if known)	Publication Date/Filing Date MM-DD-YYYY	Applicant of Cited Document	Where Relevant Passages or Relevant Figures Appear	T ⁶
	AB	WO 90/04403	05-03-1990	Univ. of Calif.		
	AC	WO 95/35038	12-28-1995	Singer		
	AD	JP 06 345660	12-20-1994	Earth Seiyaku KK		
	AE	JP 06 345664	12-20-2004	Tomita		
	-					

Examiner Signature	Date Considered	

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. \(^1\) Applicant's unique citation designation number (optional). \(^2\) See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. \(^3\) Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). \(^4\) For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. \(^5\) Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. \(^6\) Applicant is to place a check mark here if English language Translation is attached.

Translation is attached.

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

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PTO/SB/08b(08-03)

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Substitute	for form 144	9B/PTO				
11150	DIAT	ON 016	OL COURT	Application Number .	10/510,370	
			SCLOSURE	Filing Date	May 9, 2005	
STAT	TEMEN	T BY A	PPLICANT	First Named Inventor	Donald Johnstone Naismith	
				Art Unit	To Be Determined	
(Use as many sheets as necessary)				Examiner Name	To Be Determined	
Sheet	2	of	4	Attorney Docket Number	BTG0005-100 (143593US01)	

		NON PATENT LITERATURE DOCUMENTS	
Examiner Initials *	Cite No.1	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T²
	AF	Appel et al., "A clinical trial of the effects of dietary patterns on blood pressure," N. Engl. J. Med., (1997) 336:1117-1124.	
	AG	Bates et al., "Micronutrients: highlights and research challenges from the 1994-5 National Diet and Nutrition Survey of people aged 65 years and over," Br. J. Nutr. (1999) 82:7-15.	
	АН	Boegehold et al., "Importance of Dietary Chloride for Salt Sensitivity of Blood Pressure," Hypertension (1991) 17(1 Suppl):158-161.	
	AI	Cappuccio et al., "Does potassium supplementation lower blood pressure? A meta- analysis of published trials.," J. Hypertens. (1991) 9:465-473.	
	AJ	Dyer et al., "Body mass index and associations of sodium and potassium with blood pressure in INTERSALT," Hypertension (1994) 23:729-736.	
	AK	Freedman et al., "Salt and blood pressure. Conventional wisdom reconsidered," Eval. Rev. (2001) 25:267-287.	
	AL	Frisancho et al., "Blood pressure in blacks and whites and its relationship to dietary sodium and potassium intake," J. Chronic. Dis. (1984) 37:515-519.	-
	AM	Geleijnse et al., "Sodium and potassium intake and blood pressure change in childhood," Brit. Med. J. (1990) 300:899-902.	
	AN	Giaconi et al., "Seasonal influences on blood pressure in high normal to mild hypertensive range," Hypertension (1989) 14:22-27.	
	AO	Graudal et al., "Effects of sodium restriction on blood pressure, renin, aldosterone, catecholamines, cholesterols, and triglyceride: a meta-analysis," J. Amer. Med. Assoc. (1998) 279:1383-1391.	
	AP	Gregory et al., The Dietary and Nutritional Survey of British Adults, HMSO London (1990) 154-158.	

Examiner	Date	
Signature	Considered	

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance

and not considered. Include copy of this form with next communication to applicant.

Applicant's unique citation designation number (optional). Applicant is to place a check mark here if English language Translation is attached. This collection of information is required by 37 CFR 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 120 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

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Substitute for form 1449B/PTO				Complete if K	
11150	DILAT	ON DIO	OL COLIDE	Application Number	10/210 370
			CLOSURE	Filing Date	May 9, 2005
STATEMENT BY APPLICANT			PPLICANT	First Named Inventor	Donald Johnstone Naismith
				Art Unit	To Be Determined
(Use as many sheets as necessary)			necessary)	Examiner Name	To Be Determined
Sheet	3	of	4	Attorney Docket Number	BTG0005-100 (143593US01)

	NON PATENT LITERATURE DOCUMENTS					
Examiner Initials *	Cite No.1	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T²			
	AQ	Jansen et al., "The effect of a change in ambient temperature on blood pressure in normotensives," J. Hum. Hypertens. (2001) 15:113-117.				
	AR	Kannel., "Blood pressure as a cardiovascular risk factor: prevention and treatment," J. Amer. Med. Assoc. (1996) 275:1571-1576.				
	AS	Kawano et al., "Effects of potassium supplementation on office, home and 24-H blood pressure in patients with essential hypertension," Am. J. Hypertens. (1998) 10(11):1141-1146.				
	AT	Koneth et al., "Potassium and Arterial Hypertension – are Potassium Supplements Useful?" Schweizerische Rundschau Fuer Medizin Praxis (2000) 38(89):1499-1505. (German).				
	AU	Kotchen et al., "Dietary sodium and blood pressure: interactions with other nutrients," Am. J. Clin. Nutr. (1997) 65(2Suppl):7085-711S.				
	AV	Langford, "Dietary potassium and hypertension: epidemiologic data," Ann. Intern. Med. (1983) 98:770-772.				
	AW	Materson et al., "Single-drug therapy for hypertension in men. A comparison of six antihypertensive agents with placebo," N. Engl. J. Med. (1993) 328:914-921.				
	AX	Matlou et al., "Potassium supplementation in blacks with mild to moderate essential hypertension," J. Hypertens. (1986) 4:61-64.				
	AY	Morris et al., "Normotensive salt sensitivity: effects of race and dietary potassium," Hypertension (1999) 33:18-23.				
	AZ	Sacks et al., "Low blood pressure in vegetarians: effects of specific foods and nutrients," Am. J. Clin. Nutr. (1988) 48(3 Suppl):795-800.				
	ВА	Sacks et al., "Effects on blood pressure of reduced dietary sodium and the Dietary Approaches to Stop Hypertension (DASH) diet," N. Engl. J. Med. (2001) 344:3-10.				

Examiner Signature	Date Considered	
L -	 	

^{*}EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance

^{*}EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

Applicant's unique citation designation number (optional). Applicant is to place a check mark here if English language Translation is attached. This collection of information is required by 37 CFR 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 120 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

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PTO/SB/08b(08-03)

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Substitute for form 1449B/PTO				Complete if Known		
INFORMATION DISCLOSURE				Application Number	103510 370	
				Filing Date	May 9, 2005	
STATEMENT BY APPLICANT			PPLICANT	First Named Inventor	Donald Johnstone Naismith	
				Art Unit	To Be Determined	
(Use as many sheets as necessary)			necessary)	Examiner Name	To Be Determined	
Sheet	4	of	4	Attorney Docket Number	BTG0005-100 (143593US01)	

	NON PATENT LITERATURE DOCUMENTS					
Examiner Initials *	Cite No.1	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T²			
	ВВ	Shore et al., "A randomized crossover study to compare the blood pressure response to sodium loading with and without chloride in patients with essential hypertension," J. Hypertens. (1988) 6:613-617.				
	ВС	Siani et al., "Controlled trial of long term oral potassium supplements in patients with mild hypertension," Br. Med. J. (Clin. Res. Ed.) (1987) 294:1453-1456. Double check author's name				
	BD	Sinaiko et al., "Effect of low sodium diet or potassium supplementation on adolescent blood pressure," Hypertension (1993) 21:989-994.				
	BE	Smith et al., "Socio-economic differentials in health: the role of nutrition," <i>Proc. Nutr. Soc.</i> (1997) 56:75-90.				
	BF	Rouse et al., "Blood-pressure-lowering effect of a vegetarian diet: controlled trial in normotensive subjects," <i>Lancet</i> (1983) 1:5-10.				
	BG	Ward et al., "Tokelau Island Migrant Study," Hypertension (1980) 2(Suppl. 1):43-54.				
	ВН	Watanabe et al., "Potassium and Hypertension," Nutrition Reviews (1998) 5 (Part 1, No. 56):151-153.	=			
	BI	Whelton, "Epidemiology of hypertension," Lancet (1994) 344:101-106.				
	ВЈ	Whelton et al., "Effects of oral potassium on blood pressure. Meta-analysis of randomized controlled clinical trials," J. Amer. Med. Assoc. (1997) 277:1624-1632.				
	ВК	Wilson et al., "Effects of potassium on blood pressure in salt-sensitive and salt-resistant black adolescents," <i>Hypertension</i> (1999) 34:181-186.				
	BL	International Search Report dated August 6, 2003 for International Application No. PCT/GB03/01512.				

$\overline{}$		
Examiner	Date	
Signature	 Considered	

^{*}EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance

and not considered. Include copy of this form with next communication to applicant.

Applicant's unique citation designation number (optional).

Applicant is to place a check mark here if English language Translation is attached.

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